

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU, LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

C.A. No. 21-1015-GBW

**REDACTED PUBLIC
VERSION**

SAREPTA THERAPEUTICS, INC. and
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiff,

v.

NIPPON SHINYAKU CO., LTD.
and NS PHARMA, INC.,

Plaintiff/Counter-Defendants.

MEMORANDUM OPINION AND SPECIAL MASTER ORDER #5

Before the Special Master are five discovery disputes between Nippon Shinyaku, Ltd. and NS Pharma, Inc. (collectively, “Nippon Shinyaku”) and Sarepta Therapeutics, Inc. (“Sarepta”) and University of Western Australia (“UWA”). The table below lists the five disputes and the movant for each.

DISPUTES	MOVANT
1. Motion to compel Sarepta to produce a corporate designee to testify regarding Topics Nos. 67 and 92 of Nippon Shinyaku’s 30(b)(6) Notice to Sarepta	Nippon Shinyaku
2. Motion to compel Sarepta to produce information sufficient to show the [REDACTED] for the accused product, Vyondys53, as compared	Nippon Shinyaku

with Sarepta's other exon-skipping products, [REDACTED]	
3. Motion to compel UWA to produce non-privileged documents responsive to Nippon Shinyaku's Requests for Production and disclose to Nippon Shinyaku any search terms used to locate responsive documents	Nippon Shinyaku
4. Motion to compel UWA to produce a corporate designee to testify in Delaware regarding Topics Nos. 9, 13, 14, 16, 21, 24, 25, 26, 27, 29, 31, 32, 33, 34, 40, 41, 43, 44, 45, 46, 47, 48, 50, 51, 52, 57, 58, and 59 of Nippon Shinyaku's 30(b)(6) Notice to UWA	Nippon Shinyaku
5. Motion to compel Nippon Shinyaku to produce: (i) a Rule 30(b)(6) witness to provide testimony on three research reports in Nippon Shinyaku's custody (NS00102924-987, NS00102988-3060, NS000103061-110, collectively the "CERI Reports") and (ii) all documents relating to the CERI Reports and any correspondence within Nippon Shinyaku, between Nippon Shinyaku and the Chemical Evaluation and Research Institute, and between Nippon Shinyaku and any other entity or individual, regarding the CERI Reports	Sarepta

On August 15, 2023, each party submitted motions for the disputes where it is the movant. D.I. 342, 343. The parties also submitted letter briefing on each of the motions, and the Special Master held a transcribed videoconference hearing on August 24, 2023. D.I. 306. This Memorandum Opinion and Order addresses the parties' motions.

Having considered the letter briefs and arguments presented by the parties, for the reasons set forth below, **IT IS HEREBY ORDERED** that: (1) Nippon Shinyaku's motion to compel Sarepta to produce a corporate designee to testify regarding Nippon Shinyaku's Rule 30(b)(6) Topics Nos. 67 and 92 is **DENIED** (D.I. 342); (2) Nippon Shinyaku's motion to compel Sarepta to produce information sufficient to show [REDACTED] for the accused product, Vyondys53, as compared with Sarepta's other exon-skipping products,

██████████ is **DENIED** (D.I. 342); (3) Nippon Shinyaku's motion to compel UWA to produce documents responsive to Nippon Shinyaku's requests for production and to disclose search terms used to locate responsive documents is **DENIED** (D.I. 342); (4) Nippon Shinyaku's motion to compel UWA to produce a corporate designee to testify in Delaware regarding Nippon Shinyaku's Rule 30(b)(6) Topics Nos. 9, 13, 14, 16, 21, 24, 25, 26, 27, 29, 31, 32, 33, 34, 40, 41, 43, 44, 45, 46, 47, 48, 50, 51, 52, 57, 58, and 59 is **GRANTED IN PART** (D.I. 342); and (5) Sarepta's motion to compel to Nippon Shinyaku to produce a Rule 30(b)(6) witness to provide testimony on the CERI Reports and documents relating to the CERI Reports is **GRANTED IN PART** (D.I. 343).

I. BACKGROUND

This case involves cross-assertions of patent infringement. Nippon Shinyaku asserts infringement of seven patents against Sarepta, and Sarepta and UWA assert infringement of three patents against Nippon Shinyaku. Fact discovery is closed and expert discovery is scheduled to be completed on November 20, 2023. D.I. 143, 341.

II. LEGAL STANDARD

“Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.” Fed. R. Civ. P. 26(b)(1). “Generally, a party moving to compel bears the burden of demonstrating the relevance

of the requested information.” *Delaware Display Group LLC v. Lenovo Group Ltd.*, No. 13-2018-RGA, 2016 WL 720977, at *2 (D. Del. Feb. 23, 2016).

III. DISCUSSION

A. Nippon Shinyaku’s Motion to Compel Sarepta to Produce a Corporate Designee to Testify Regarding Nippon Shinyaku’s Rule 30(b)(6) Topics Nos. 67 and 92 (Dispute 1)

Nippon Shinyaku argues that Sarepta should be compelled to produce a corporate designee to testify in response to Rule 30(b)(6) Topics Nos. 67 (“The commercial success of the Accused Sarepta Product in the U.S. since the first date of use, sale, and/or importation into the U.S.”) and 92 (“The factual basis for UWA’s arguments and submissions made in Interference No. 106,007 before the Patent Trial and Appeal Board”). Nippon Shinyaku’s Opening Brief at 1, Ex. 1.

Regarding Topic No. 67, Nippon Shinyaku argues that Sarepta should be compelled to produce a 30(b)(6) witness on this topic because commercial success of the accused Vyondys53 product is relevant to both non-obviousness and patent infringement damages, and is a topic on which parties in patent litigation routinely provide 30(b)(6) testimony. *Id.* at 1, 2. Nippon Shinyaku contends that it does not seek Sarepta’s legal contentions regarding commercial success, but instead seeks 30(b)(6) testimony regarding “Sarepta’s assessment of its own product’s commercial success.” *Id.* at 1.

Regarding Topic No. 92, Nippon Shinyaku argues that Sarepta should be compelled to produce a 30(b)(6) witness on this topic because the patent at issue in Interference No. 106,007 (the “’007 Interference Proceeding”) is from the same patent family as the three UWA Patents asserted by Sarepta and UWA in this litigation, and Sarepta controlled the ’007 Interference Proceeding prosecuted under UWA’s name. *Id.* at 2. Nippon Shinyaku contends that during the

'007 Interference Proceeding, UWA made certain arguments regarding the scope of the claims at issue in that proceeding relating to written description and enablement, and as such, UWA and Sarepta are judicially estopped from making contradictory arguments regarding similar claims in this litigation. Nippon Shinyaku's Opening Brief at 2-3. Nippon Shinyaku argues that it should be permitted via Rule 30(b)(6) testimony to explore "Sarepta's and UWA's bases for making those assertions in the first instance." *Id.* at 3.

In response, Sarepta argues that Nippon Shinyaku's motion should be denied because the 30(b)(6) topics upon which Nippon Shinyaku seeks testimony are irrelevant to this case. Sarepta's Answering Brief at 1. Regarding Topic No. 67, Sarepta argues that this topic is irrelevant because

[REDACTED] *Id.* at 2. Sarepta also argues that commercial success is a contention-related topic, and contention depositions are not permitted in the District of Delaware. *Id.* at 3 (citing *Int'l Bus. Machs. Corp. v. Priceline Grp.*, No. 15-137-LPS, 2016 WL 6305981, at *2 (D. Del. Sept. 29, 2016) (denying motion to compel on "de facto contention deposition categories"))).

Regarding Topic No. 92, Sarepta argues that this topic is irrelevant because the patent involved in the '007 Interference Proceeding is not one of the patents asserted in this case and involves claims having a different scope than the claims at issue here. Sarepta's Answering Brief at 3. Sarepta also argues that because this case arises out of different causes of action, there is no judicial estoppel between this litigation and the '007 Interference Proceeding. *Id.* Sarepta notes that Nippon Shinyaku had also previously represented to the Court that the patent at issue in the '007 Interference Proceeding "is not directly related to and claims a different genus of AOs." *Id.* at 4.

Nippon Shinyaku's motion is **DENIED** as to both Topics Nos. 67 and 92. Regarding Topic No. 67, the Special Master is not persuaded that the 30(b)(6) testimony on commercial success Nippon Shinyaku seeks is relevant and proportional to the needs of this case, particularly given that [REDACTED]

[REDACTED] To the extent that the discovery on commercial success Nippon Shinyaku seeks may have some relevance, such discovery is better obtained through contention interrogatories and expert testimony, rather than by Rule 30(b)(6) deposition testimony. Although Nippon Shinyaku states that it does not seek Sarepta's legal contentions regarding commercial success and seeks only Sarepta's assessment of its own product's success, commercial success is nonetheless a contention topic on which 30(b)(6) deposition testimony is not permitted in this District. *See, e.g., Axiohm IPS, Inc. v. Epson Am. Inc.*, C.A. No. 00-420-SLR, Tr. 4:14-15 (D. Del. Mar. 28, 2001).

Regarding Topic No. 92, the Special Matter is not persuaded that the 30(b)(6) testimony Nippon Shinyaku seeks regarding UWA's arguments and submissions made in the '007 Interference Proceeding is relevant and proportional to the needs of this case. Although Nippon Shinyaku argues that UWA made certain arguments regarding the scope of the claims at issue in that interference proceeding, Nippon Shinyaku does not adequately explain why 30(b)(6) testimony on those arguments is necessary and relevant to this case. For example, Nippon Shinyaku does not meaningfully address important differences between the two cases, namely that the patent involved in the '007 Interference Proceeding is not one of the patents asserted in this case, and the claims at issue in the interference proceeding have a different scope than the claims at issue in this litigation. Given such differences between the two proceedings, including that this case arises out of different causes of action, Nippon Shinyaku has not adequately demonstrated

that obtaining 30(b)(6) testimony on this topic, and any potential probative value it may possibly have, is proportional to the needs of the case. The fact that the patent at issue in the '007 Interference Proceeding is from the same patent family as the three UWA Patents asserted in this litigation or that Sarepta may have had some involvement in that proceeding, without more, is insufficient to satisfy Nippon Shinyaku's burden in this regard. Also, contrary to what Nippon Shinyaku argues, UWA and Sarepta are not judicially estopped from making arguments regarding the scope of the claims in this litigation that may differ from arguments made regarding the scope of the claims at issue in the '007 Interference Proceeding. *See Evonik Degussa GmbH v. Materia Inc.*, 53 F. Supp. 3d 778, 795-96 (D. Del. 2014).

Accordingly, Nippon Shinyaku's motion to compel Sarepta to produce a corporate designee to testify regarding Rule 30(b)(6) Topics Nos. 67 and 92 is **DENIED**.

B. Nippon Shinyaku's Motion to Compel Sarepta to Produce Information Sufficient to Show [REDACTED] for the Accused Product, Vyondys53, as Compared with Sarepta's Other Exon-Skipping Products, [REDACTED] (Dispute 2)

Nippon Shinyaku argues that Sarepta should be compelled to provide information sufficient to show [REDACTED] for the accused product, Vyondys53, as compared with Sarepta's other exon-skipping products, [REDACTED]. Nippon Shinyaku's Opening Brief at 3. Nippon Shinyaku expects the requested information to be probative of [REDACTED] when compared to Sarepta's other exon skipping therapies that do not face direct market competition. *Id.* at 3-4. Nippon Shinyaku also expects the requested information regarding [REDACTED] will show

[REDACTED]

[REDACTED]. *Id.* at 6. Nippon Shinyaku notes that the requested information was previously available to it through unredacted [REDACTED] Sarepta had previously produced, but that Sarepta had recently clawed back from the reports [REDACTED] [REDACTED] on relevance grounds. *Id.* at 4.

Nippon Shinyaku argues that the information it seeks is responsive to 30(b)(6) Topics Nos. 105 and 106, and relevant to “[t]he extent to which the infringer has made use of the invention; and any evidence probative of the value of that use,” as part of the *Georgia-Pacific* factors and hypothetical negotiation framework for determining reasonable royalty damages. Nippon Shinyaku’s Opening Brief at 4, 5 (citing *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970)). Nippon Shinyaku also argues that this request is proportional to the needs of the case because it “does not seek to entirely undo Sarepta’s clawback and re-obtain [REDACTED], but has narrowly tailored its request to the particular information it needs to complete the picture regarding [REDACTED] [REDACTED].” *Id.* at 6.

In response, Sarepta argues that Nippon Shinyaku’s motion should be denied because it improperly seeks to compel irrelevant, commercially sensitive information that Sarepta properly clawed back under the Protective Order. Sarepta’s Opening Brief at 4. Sarepta contends that Nippon Shinyaku is seeking to use redacted, confidential information that had previously been inadvertently produced, and then subsequently clawed back by Sarepta. *Id.* at 5. Sarepta contends that the now-redacted, confidential material is irrelevant because it relates to [REDACTED] [REDACTED], which are products not accused of infringement in this litigation. *Id.* Sarepta further contends that [REDACTED]

██████████ has nothing to do with the claims and defenses in this case and Nippon Shinyaku's reference to the *Georgia-Pacific* factors does not justify disclosure of a direct competitor's confidential, commercially sensitive business information. *Id.*

Nippon Shinyaku's motion is **DENIED**. The Special Master is not persuaded that the information Nippon Shinyaku seeks is relevant and proportional to the needs of this case particularly given that the information relates to non-accused products, was inadvertently produced, and properly clawed back by Sarepta under the parties' Protective Order. Although Nippon Shinyaku argues that the information is necessary to "complete the picture regarding ██████████" (Nippon Shinyaku's Opening Brief at 6), Nippon Shinyaku does not adequately explain or provide persuasive authority to justify disregarding the claw back provisions of the Protective Order under these circumstances.

Further, Nippon Shinyaku does not dispute that the information it seeks is confidential and commercially sensitive, and relates to ██████████ not accused of infringement in this case. Nippon Shinyaku also does not dispute that Sarepta properly clawed back the requested information in accordance with the terms of the parties' Protective Order, and that it did not challenge or object to Sarepta's claw back of that information. 8/24/2023 Hearing Transcript at 27:10-19, 28:3-12. In light of these facts, the Special Master is not persuaded that Nippon Shinyaku has demonstrated sufficient basis to compel Sarepta to produce the now-redacted and properly clawed back information relating to Sarepta's non-accused products.

The Special Master is also not persuaded Nippon Shinyaku has demonstrated that the information it seeks is particularly relevant to any of the claims and issues in this case. Although Nippon Shinyaku contends that the information it seeks is probative of the *Georgia-Pacific* hypothetical negotiation factors (Nippon Shinyaku's Opening Brief at 4-5), Nippon Shinyaku does

not adequately explain how or why such information relating to non-accused products involving different exon-skipping therapies and patient treatments are relevant and proportional to the needs of this case. Nippon Shinyaku's statements that "it expects the requested information to be probative of [REDACTED]" (*id.* at 3-4) and to "show that [REDACTED]" (*id.* at 6) are speculative and, without more, insufficient to satisfy Nippon Shinyaku's burden in this regard.

Accordingly, Nippon Shinyaku's motion to compel Sarepta to provide information sufficient to show [REDACTED] for the accused product, Vyondys53, as compared with Sarepta's non-accused [REDACTED] is **DENIED.**

C. Nippon Shinyaku's Motion to Compel UWA to Produce Documents Responsive to Nippon Shinyaku's Requests for Production and to Disclose Search Terms Used to Locate Responsive Documents (Dispute 3)

Nippon Shinyaku argues that UWA should be compelled to search for and produce non-privileged documents responsive to Nippon Shinyaku's Requests for Production because UWA has delayed participation in discovery at all, refused to conduct searches, and has refused to confirm that it has searched for and produced non-privileged documents responsive to each of Nippon Shinyaku's document requests. Nippon Shinyaku's Opening Brief at 6, 7. In particular, Nippon Shinyaku contends that UWA has not produced certain categories of documents that a licensor, such as UWA, would have typically produced, including, for example, "[REDACTED]", license negotiation documents, assignments and amendment agreements for the UWA patents, and market projections." *Id.* at 6. Nippon Shinyaku

further contends that, in light of these apparently missing documents from UWA's production, UWA should be compelled to comply with paragraph 5(b) of the D. Del. Default Standard for Discovery and disclose what, if any, search terms it used to search for documents responsive to the requests for production. *Id.* at 7.

In response, UWA argues that Nippon Shinyaku's motion should be denied because UWA has produced all relevant, non-privileged documents in its custody and control located after a reasonable search. UWA's Answering Brief at 5-6. UWA maintains that Nippon Shinyaku has already received 36,424 pages of documents from UWA and UWA's former employees, and more than sixty laboratory notebooks recording work from UWA produced by Sarepta. *Id.* at 6. UWA further represents that, beyond the documents it has recently produced, it is unaware of any other responsive, non-privileged documents in its custody and control. *Id.*

In view of UWA's representation on the record that it has produced all relevant, non-privileged documents in its custody and control located after a reasonable search, and that beyond the documents it has recently produced, it is unaware of any other responsive, non-privileged documents in its custody and control, Nippon Shinyaku's motion to compel Sarepta to produce documents responsive to Nippon Shinyaku's Requests for Production and to disclose search terms used to locate responsive documents is **DENIED**. The Special Master finds UWA's representations regarding having produced responsive documents after having conducted a reasonable search sufficient to satisfy its discovery obligations in this regard.

D. Nippon Shinyaku's Motion to Compel UWA to Produce a Corporate Designee to Testify in Delaware Regarding Nippon Shinyaku's Rule 30(b)(6) Topics Nos. 9, 13, 14, 16, 21, 24, 25, 26, 27, 29, 31, 32, 33, 34, 40, 41, 43, 44, 45, 46, 47, 48, 50, 51, 52, 57, 58, and 59 (Dispute 4)

Nippon Shinyaku argues that UWA should be compelled to produce a 30(b)(6) designee to testify in response to Rule 30(b)(6) Topics Nos. 9, 13, 14, 16, 21, 24, 25, 26, 27, 29, 31, 32, 33, 34, 40, 41, 43, 44, 45, 46, 47, 48, 50, 51, 52, 57, 58, and 59. Nippon Shinyaku's Opening Brief at 7. Nippon argues that these topics are relevant to the issues in this case and UWA has failed to show why producing a corporate designee to testify on them is unduly burdensome or otherwise improper. *Id.* at 7-9.

Nippon Shinyaku groups the 30(b)(6) topics at issue into categories: Topics Nos. 9, 43, 44, 46, 47, 52, 58, and 59 relate to UWA's license agreements, contracts, [REDACTED] and licensing practices with Sarepta ("Licensing-Related Topics"); Topics Nos. 13 and 16 relate to infringement and validity questions regarding the patents-in-suit and UWA's analyses of Nippon Shinyaku's accused product ("Infringement-Related Topics"); Topics Nos. 21 and 34 relate to UWA's conception and reduction to practice of the patents-in-suit ("Conception and Reduction to Practice Topics"); Topics Nos. 24 and 25 relate to enablement and written description of the patents-in-suit ("Enablement and Invention Disclosure Topics"); Topic No. 26 relates to the prosecution history of the patents-in-suit ("Prosecution History Topic"); Topics Nos. 29, and 31-33 relate to the scope of prior art ("Prior Art-Related Topics"); Topics Nos. 40, 41, 45, 48, 50, and 51 relate to damages-related issues, including, licenses for the patents-in-suit, licensing policies, and the market for sales ("Damages-Related Topics"); Topic No. 57 relates to non-privileged communications between UWA and Sarepta or third parties pertaining to this action and related proceedings ("Litigation and Related Proceedings Topic"); and Topics Nos. 14 and 27 relate to interference proceedings involving the patents-in-suit ("Interference Proceedings Topics"). *Id.* at 7-9, Ex. 14.

In response, UWA argues that Nippon Shinyaku's motion should be denied because UWA has no further corporate knowledge relating to these 30(b)(6) topics and cannot compel any former

employees to testify. UWA's Answering Brief at 7. UWA provides further arguments regarding the 30(b)(6) topics by category:

1. Licensing-Related Topics. Regarding the Licensing-Related Topics, UWA argues that Nippon Shinyaku's motion should be denied because there are no current UWA employees that were involved in the negotiation of the licenses and agreements and there exists no UWA corporate knowledge to transfer to a witness. UWA's Answering Brief at 7. As to former employees and efforts to ascertain such knowledge, UWA maintains that, under Australian law, it cannot legally compel former employees to testify in a U.S. litigation, and preparation of a current corporate designee to fly from Australia to the U.S. merely to say "I don't know" in response to deposition questioning is impractical and imposes a substantial burden. *Id.* at 7-8.

Nippon Shinyaku's motion as to the Licensing-Related Topics (Topics Nos. 9, 43, 44, 46, 47, 52, 58, and 59) is **GRANTED IN PART** to the extent it seeks to compel UWA to produce a corporate designee to provide testimony regarding UWA's license agreements, contracts, [REDACTED], and licensing practices with Sarepta involving the patents-in-suit. Although UWA contends that it has no further corporate knowledge relating to these topics and cannot compel any former employees to testify, UWA nonetheless has an obligation under the Federal Rules to make reasonable efforts to ascertain information, and to identify and prepare a 30(b)(6) witness to testify on these relevant topics. On this record, the Special Master is not persuaded UWA has made sufficient efforts. For example, with the exception of one witness, UWA does not discuss any meaningful efforts it has made to obtain information regarding any of these topics from former employees. *See* 8/24/2023 Hearing Transcript at 31:15-32:1, 35:13-36:1, 38:1-19. The Special Master is persuaded that with some further effort, non-privileged information regarding UWA's current license agreements, contracts, [REDACTED] and licensing practices with Sarepta concerning

the patents-in-suit should be reasonably ascertainable by UWA, and that these are topics relevant to the issues in this case, and appropriate for Nippon Shinyaku to seek 30(b)(6) deposition testimony.

2. Infringement-Related Topics. Regarding the Infringement-Related Topics, UWA argues that Nippon Shinyaku's motion should be denied because these topics seek privileged information and Nippon Shinyaku has not addressed UWA's vagueness objections. UWA's Answering Brief at 8. Nippon Shinyaku's motion as to the Infringement-Related Topics is **DENIED** because the Special Master agrees that these topics seek privileged information and are essentially infringement contention deposition topics, which, as discussed above, are not permitted in this District. Topic No. 13, for example, covers among other things, "Documents or Communications before July 13, 2021 that allege or discuss infringement of the UWA Patents." Nippon Shinyaku's Opening Brief at Ex. 14. Topic No. 16 covers "Any analysis prepared by UWA concerning the Accused NS Product." *Id.*

3. Prosecution History Topic. Regarding the Prosecution History Topic, UWA argues that, in addition to no current UWA employee having any non-privileged information regarding prosecution, Nippon Shinyaku has already deposed UWA's outside prosecution counsel on this topic and the parties had previously agreed that discovery relating to prosecution would be limited to the production of certified file histories. UWA's Answering Brief at 9. In view of UWA's representation that Nippon Shinyaku has already deposed UWA's outside prosecution counsel on this topic and the parties previously agreed that discovery relating to prosecution would be limited to the production of certified file histories, Nippon Shinyaku's motion as to the Prosecution History Topic (Topic No. 26) is **DENIED**.

4. Damages-Related Topics. Regarding the Damages-Related Topics, UWA argues that all of the topics are wholly or partly duplicative of topics Nippon Shinyaku already served on Sarepta or, in the case of Topic No. 40, an improper contention topic. UWA's Answering Brief at 10.

Nippon Shinyaku's motion as to certain of the Damages-Related Topics (Topics Nos. 40, 41, 48, 50, and 51) is **GRANTED IN PART** to the extent it seeks to compel UWA to produce a corporate designee to provide testimony regarding UWA's current licenses for the patents-in-suit, licensing policies, and the market for sales relating to the patents-in-suit. The Special Master is persuaded that with some further effort, non-privileged information regarding UWA's current licenses for the patents-in-suit, licensing policies, and the market for sales relating to the patents-in-suit should be reasonably ascertainable by UWA, and that these are topics relevant to the issues in this case, and appropriate for Nippon Shinyaku to seek 30(b)(6) deposition testimony. The Special Master is not persuaded that Topic No. 40 is an improper contention topic because, on its face, it does not appear to seek any of UWA's legal contentions or expert testimony regarding any issues in the case.

5. Litigation and Related Proceedings Topic. Regarding Topic No. 57, UWA contends that it has no non-privileged communications regarding this case or the interference proceeding and that any information that Nippon Shinyaku would gain by deposing a 30(b)(6) witness on this topic is minimal and would not justify the burden of preparing a UWA witness. UWA's Answering Brief at 10. In view of UWA's representation that it has no non-privileged communications regarding this case or the interference proceeding, Nippon Shinyaku's motion as to the Litigation and Related Proceedings Topic (Topic No. 57) is **DENIED**.

6. Interference Proceedings Topics. Regarding Topics Nos. 14 and 27, UWA argues that Nippon Shinyaku's motion to compel should be denied for the same reasons discussed above with respect to Dispute 1. UWA's Answering Brief at 10. The Special Master agrees. Nippon Shinyaku's motion as to the Interference Proceedings Topics (Topics Nos. 14 and 27) is **DENIED** for the same reasons discussed above for Dispute 1.

7. Other 30(b)(6) Topics. With respect to the remaining categories of 30(b)(6) topics (Conception and Reduction to Practice Topics, Enablement and Invention Disclosure Topics, and Prior Art Topics), UWA argues that Nippon Shinyaku's motion should be denied because they are contention deposition topics, which are not allowed in the District of Delaware. UWA's Answering Brief at 9-10 (citing *Axiom IPS, Inc. v. Epson Am. Inc.*, C.A. No. 00-420-SLR, Tr. 4:14-15 (D. Del. Mar. 28, 2001) ("[W]e don't do contention depositions in this district.")).

The Special Master agrees with UWA's argument in this regard. That is, that these topics are contention deposition topics, which are not permitted in this District. Nippon Shinyaku's motion as to the Conception and Reduction to Practice Topics (Topics Nos. 21 and 34), Enablement and Invention Disclosure Topics (Topics No. 24 and 25), and Prior Art Topics (Topics Nos. 29 and 31-33) is therefore **DENIED**.

Accordingly, Nippon Shinyaku's motion to compel UWA to produce a corporate designee to testify is **GRANTED IN PART** as to the Licensing-Related Topics (Topics Nos. 9, 43, 44, 46, 47, 52, 58, and 59) and certain of the Damages-Related Topics (Topics Nos. 40, 41, 48, 50, and 51). The motion to compel is otherwise **DENIED** as to the remaining Rule 30(b)(6) Topics Nos. 13, 14, 16, 21, 24, 25, 26, 27, 29, 31, 32, 33, 34, 45, and 57.

IT IS HEREBY ORDERED that UWA shall produce a corporate designee to testify regarding Nippon Shinyaku's Rule 30(b)(6) Topics Nos. 9, 40, 41, 43, 44, 46, 47, 48, 50, 51, 52,

58, and 59 in Delaware (or other mutually agreed upon location) within twenty-one (21) days of this Memorandum Opinion and Order. The parties may also mutually agree to conduct the deposition remotely via Zoom.

E. Sarepta's Motion to Compel to Nippon Shinyaku to Produce a Rule 30(b)(6) Witness to Provide Testimony on the CERI Reports and Documents Relating to the CERI Reports (Dispute 5)

Sarepta argues that Nippon Shinyaku should be compelled to produce: (1) a Rule 30(b)(6) witness to provide testimony on the CERI Reports and (2) all documents relating to the CERI Reports. Sarepta's Opening Brief at 1, 4. Sarepta contends that days after Nippon Shinyaku's Rule 30(b)(6) witness testified on topics relating to testing of exon 53 antisense oligonucleotides, Nippon Shinyaku produced three technical reports from the Chemical Evaluation and Research Institute (CERI) in Japan, evaluating exon 53 targeting antisense oligonucleotides. *Id.* at 1-2. Sarepta further contends that according to the metadata provided by Nippon Shinyaku, the three CERI Reports were in Nippon Shinyaku's custody and, according to Nippon Shinyaku's counsel, Nippon Shinyaku had sponsored the studies reflected in the reports. *Id.* at 2-3. Sarepta also contends that after producing the three CERI documents, Nippon Shinyaku expressly relied on the documents in its Final Invalidity Contentions in contending that the patents asserted by Sarepta are invalid. *Id.* at 1, 3; 8/24/2023 Hearing Transcript at 46:6-18.

Sarepta further argues that by withholding the production of these CERI Reports, Nippon Shinyaku has foreclosed Sarepta's opportunity to examine the documents with Nippon Shinyaku's Rule 30(b)(6) witness and meaningfully explore the CERI Reports and all related documents in fact discovery. Sarepta's Opening Brief at 1, 5-6. Sarepta maintains that because Nippon Shinyaku chose to produce the CERI Reports in challenging the validity of the patents asserted by Sarepta,

Nippon Shinyaku should be compelled to produce a Rule 30(b)(6) witness and all documents and communications relating to the CERI Reports, regardless of whether these documents were prepared for litigation or involved counsel. *Id.* at 6 (citing cases).

In response, Nippon Shinyaku argues that Sarepta's motion should be denied because the experiments in the CERI Reports were designed and conducted by a third party contract research organization under the guidance of Nippon Shinyaku's technical expert, Dr. Michele Hastings. Nippon Shinyaku's Answering Brief at 1. Nippon Shinyaku contends that CERI began the experiments set forth in the CERI Reports on February 3, 2022, March 31, 2022, and October 19, 2022—after this litigation commenced—and completed the studies on May 17, 2023. *Id.* Nippon Shinyaku further contends that the CERI Reports were issued in May 2023, and it moved to expeditiously produce them in June 2023, and included them in its Final Invalidity Contentions to give “clear notice of its intent to rely upon the CERI Reports. *Id.* Nippon Shinyaku maintains that it “produced the CERI Reports during fact discovery, rather than waiting to provide them as an exhibit to its expert's forthcoming report.” *Id.* at 4. Nippon Shinyaku also maintains that Sarepta will have ample opportunity to explore the studies in the CERI Reports experimental design and results in connection with expert discovery. *Id.* at 5.

Sarepta's motion to compel Nippon Shinyaku to produce a Rule 30(b)(6) witness to provide testimony on the CERI Reports and documents relating to the CERI Reports is **GRANTED IN PART** to the extent it seeks discovery of non-privileged and non-work product-protected information. Although Nippon Shinyaku contends that the CERI Reports were designed and conducted by a third party contract research organization under the guidance of its technical expert, it is undisputed that the reports are relevant to issues in the case and were produced during fact discovery. It is also undisputed that the CERI Reports relate to testing of exon 53 antisense

oligonucleotides, and that Nippon Shinyaku's relies on these documents in fact discovery as part of its invalidity challenge to the patents asserted by Sarepta. Nippon Shinyaku also does not dispute that the CERI Reports were in its custody and not included on its privilege log, and that it did not indicate in its Final Invalidity Contentions that the testing contained in the CERI Reports was performed on behalf of a testifying expert.

Given these circumstances, particularly in light of the timing of Nippon Shinyaku's production of the CERI Reports and reliance on the documents to challenge the validity of patents-in-suit, the Special Master is persuaded that Sarepta should have an opportunity to obtain some fact discovery on the CERI Reports, regardless of whether these documents were prepared for litigation or involved counsel. *See Ansell Healthcare Prods., LLC v. Reckitt Benckiser LLC*, No. 15-cv-915-RGA, 2017 WL 6328149, at *4 (D. Del. Dec. 11, 2017) (stating "privilege cannot be used both as a sword and a shield"); *see also CP Kelco U.S. Inc. v. Pharmacia Crop.*, 213 F.R.D. 176, 179 (D. Del. 2003) ("It would be manifestly unfair to allow a party to use the privilege to shield information which it had deliberately chose to use offensively . . . when it used the allegedly privileged documents to arm its expert for testimony."); 8/24/2023 Hearing Transcript at 57:4-19.

Accordingly, Sarepta's motion to compel Nippon Shinyaku to produce a Rule 30(b)(6) witness to provide testimony on the CERI Reports and documents relating to the CERI Reports is **GRANTED IN PART.**

IT IS HEREBY ORDERED that Nippon Shinyaku shall produce a Rule 30(b)(6) witness to provide testimony on the CERI Reports in Delaware (or other mutually agreed upon location in the United States) within twenty-one (21) days of this Memorandum Opinion and Order. The parties may also agree to conduct the deposition remotely via Zoom.

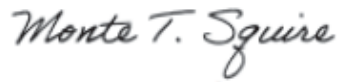
IT IS FURTHER HEREBY ORDERED that Nippon Shinyaku shall produce all non-privileged and non-work product-protected documents relating to the CERI Reports, including any correspondence within Nippon Shinyaku, between Nippon Shinyaku and the Chemical Evaluation and Research Institute, and between Nippon Shinyaku and any other entity or individual, regarding the CERI Reports within fourteen (14) days of this Memorandum Opinion and Order.

* * *

This Memorandum Opinion and Order is preliminarily submitted under seal as a precaution because portions of the underlying briefing and August 24, 2023 Hearing Transcript were marked confidential. Within three (3) business days of this Order, the parties shall jointly email the Special Master and advise of any proposed redactions.

IT IS SO ORDERED.

Dated: September 7, 2023



Special Master Monté T. Squire